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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALTER, ALYSSA M	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,891	TEHRANI, AMIR J.	
	Examiner	Art Unit	
	Alyssa M Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 92-99 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing "coupled to" in claim 92 to --adapted to be in coupled--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the applicant is claiming as the sensor. The examiner is unsure if the Applicant is claiming the sensor to be one of the "at least one electrode" and therefore be an electrode or if the Applicant intends to claim the sensor is the "at least one electrode" which is configured to sense information corresponding to the patient's respiration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 9-11, 16-18, 20-25, 27, 51-53, 55-57, 59, 61, 64-66, 68-73, 92-94 and 96-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheiner et al. (US 6,415,183). Scheiner et al. discloses a diaphragmatic pacing system, which monitors respiratory activity and stimulates the phrenic nerve when respiratory activity is below a certain level.

As to claims 1-4, 59, 71-72 and 92, in figure 1, the "tip electrode 121 and ring electrode 122 can be used for sensing respiratory activity by a method such as minute ventilation, as will be explained below, and/or for delivering diaphragm therapy by delivering an electric stimulus to phrenic nerve 102(col. 3, 38-43), which controls the patient's diaphragm. "Electrodes 121 and 122 of first lead 120 are coupled to inputs 181 and 182 on a device 170"(col. 3, 32-34). The examiner considers the device 170, to be the responsive device and the electrodes 121 and 122 to be sensors as well since they have the capability of sensing and stimulating.

As to claims 5, 57, 73 and 98, Scheiner et al. discloses in col.5, lines 44-45, the use of the patient's minute ventilation as a physiological state. The minute ventilation is the amount of new atmospheric air that has moved into the respiratory passages each minute (Hole's Human Anatomy and Physiology, pg 798). {Please see Reference U}

Therefore, since the minute ventilation is the amount of new air taken into the lungs, the examiner considers that to inherently be the inspiration rate over a one-minute time interval.

As to claims 9-10, the electrodes sense a signal, which "represents a physiological state, such as respiratory activity. The state can be a patient's minute ventilation, for example. Alternatively, it could be chest wall motion" (col. 6, lines 53-56). Since the device can detect chest wall motion, it inherently has a movement detector for detecting the expansion and contraction of the chest. The expansion and contraction of the chest is directly related to the movement of the diaphragm.

As to claims 11, 16, 20-21, 61 and 64-66, "the present system is applicable for treating respiratory ailments such as sleep apnea. The system provides for sensing a physiological state of the patient related to respiration effort using an electrode implanted in the heart. When a physiological state indicating a need for therapy is detected, an electrical stimulus is triggered by a controller, and the electrode delivers an electric stimulus to the phrenic nerve, initiating a respiratory cycle. In another embodiment, when a physiological state indicating a respiratory event is detected, the controller inhibits delivery of an electrical stimulus, which is programmed to be delivered at a predetermined rate"(col. 1 and 2, lines 65-67 and 1-9).

As to claims 17-18 and 68-70, the need for therapy arises when the respiratory rate falls below a threshold or predetermined rate. "For example (in figure 3), if the present system is used to alleviate apnea, block 302 can be set so that if the minute ventilation goes below a preselected apneic threshold set by the physician, such as 5

liters/minute, then the method goes to block 303" (col. 6, lines 61-65). According to the Applicant's specification, "hypoventilation is a condition in which the respiratory rate is pathologically low or below a desired rate"(page 1, lines 25-27).Therefore, since Scheiner et al. senses when respiration rate falls below a threshold or predetermined rate, Scheiner et al. inherently detects hypoventilation.

As to claims 22-25 and 27, the "controller 224 includes one or more microprocessors and logic circuits for execution of software or firmware instructions. The software of controller 224 is modifiable to provide different functions"(col. 6, lines 4-7). The "controller 224 can also be externally programmed" (col. 6, line 24). Figure 10 is a view of the implanted programmable pacing system. The disclosure and the drawings of Scheiner et al. refers to figure 8 as the programmable pacing system. However, the figure is actually figure 10. The examiner has inserted the reference numbers relating to figure 10. "FIG. 8 (10) shows an exemplary programmable controller system 800 (1000). System 800 (1000) is known in the art, and it includes an external programmer 801 (1001) having a transducer 802 (1002), which sends signals to controller 224 and other components in device 170. Using programmable controller system 800 (1000), a physician can change the operating mode of device 170 and controller 224. For example, it can be changed from inhibited mode to triggered mode or asynchronous mode. Other details of operating modes will be described below"(col. 6, lines 24-33). Therefore, since the system is externally programmable the system inherently has a telemetry device for telemetric means.

As to claims 51, 53, 56, 94 and 97, "the method illustrated in FIG. 4 delivers the stimulation pulse at a predetermined frequency unless the input signal indicates that the minute ventilation is above a predetermined level"(col. 7, lines 55-58). "The minute ventilation is the product of respiration rate and tidal volume"(col. 5, lines 48-49). Since the minute volume is sensed and the minute volume is the product of respiration rate and tidal volume, both respiration rate and tidal volume are inherently sensed.

As to claims 52, 55, 93 and 96, in addition to the frequency being adjustable, the pulse amplitude and duration can also be modified. "It is contemplated that, considering the factors of electrode position and power conservation, the threshold voltage needed to stimulate the phrenic nerve will be an RMS constant voltage stimulus in the range between 0.2 volts to 14 volts with a pulse duration between approximately 0.2 milliseconds to 12 milliseconds. Alternatively, a physician can choose a constant current pulse having the same approximate energy range" (col. 4-5, lines 61-67 and 1).

2. Claims 1-5, 7-8, 11-16, 61-63 and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meer (US 4,830,008). Meer discloses a method and treatment for sleep apnea by monitoring the diaphragm EMG and phrenic nerve activity and stimulates the upper airways accordingly.

As to claims 1-5, 16, 61 and 71-73, figure 4 shows two effector electrodes 32, which "stimulate various muscles in the upper airway to maintain a patent upper airway simultaneously with stimulation of the diaphragm and other accessory muscles for inspiration such as the sternomastoid muscles to cause inspiration at a predetermined rate when no inspiratory effort is sensed by the monitor 14" (col. 4 and 5, lines 65-68

and 1-2). "The effector electrode 32 also serves as a second sensor electrode" (col. 4, lines 41-42).

As to claims 7 and 62, "inspiratory effort can be monitored by monitoring contraction of the diaphragm by electromyogram, sensing nerve conduction of the phrenic nerve, i.e. monitoring action potentials, monitoring intrathoracic pressure change via a pressure transducer, or by the use of an impedance pneumogram" (col. 5, lines 17-23).

As to claims 8 and 63, "the sensor electrode 24 is placed around the cervical portion of the phrenic nerve to detect action potentials in the phrenic nerve, i.e. incipient inspiration. The electrical signal generating mechanism 16 generates electrical signals based on information obtained from the phrenic nerve to maintain a patent airway in patients with obstructive sleep-apnea syndrome. In this arrangement, the electrical signal generating mechanism 16 may also act as a phrenic nerve stimulator in patients with central sleep-apnea syndrome"(col. 5, lines 17-23).

As to claims 12 and 13, since Meer discloses sensing the phrenic nerve activity and diaphragm activity, the lack of signals from either the phrenic nerve or the diaphragm is also inherently sensed.

As to claims 14 and 15, "the inspiratory effort monitored is analyzed by comparing the contraction of the patient's inspiratory muscles to a predetermined threshold contraction" (col. 2, lines 42-45). Since the threshold is preset, the phrenic nerve activity and the diaphragm are inherently compared with a preset value.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 30-31, 34-38, 60, 75-76, 78-80 and 86 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Scheiner et al. (US 6,415,183). Scheiner et al. discloses a diaphragmatic pacing system with a pacing apparatus, device 170, which is a pulse generator. The device also contains a signal processing circuit 226 and a controller 224, which can be one or more microprocessors. In order to process the signals, there is inherently some type of temporary memory to store the inputted values.

In the alternative, Scheiner et al. discloses the claimed invention except for the implantable memory. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing apparatus as taught by Scheiner et al. with a pacing apparatus with a memory since it was known in the art that storing collected data, which can be conveyed to the physician or patient, is helpful in diagnosing and treating a patient.

2. Claims 6, 43-44, 46-50, 54, 58, 74, 89-90, 91, 95 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (US 6,415,183), as applied to claims 30-31, 34-35, 38, 60, 75-76, 78-80 and 86 above. The modified Scheiner et al. discloses the claimed invention except for sensing the expiration rate. It would have

been obvious to one having ordinary skill in the art at the time the invention was made to modify the respiration rate as taught by the modified Scheiner et al. with the expiration rate since it was known in the art to sense the expiration and inspiration activity in order to diagnosis irregularities in normal breathing patterns.

As to claims 44, 47 and 49-50, the modified Scheiner et al. discloses the claimed invention except for the tracking of patient activity compliance. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the data stored and telemetrically sent to the physician since it was known in the art to report data to the physician in order to monitor the patient's condition and modify the treatment for patient for a distant location.

As to claims 46 and 48, since information that could be sent to the physician could be patent compliance, which could be tracked by having a history stored in the memory. This physician could respond to this compliance with a change in treatment, either through stimulation modifications or pharmaceutical recommendations.

As to claims 54 and 95, the modified Scheiner et al. discloses the claimed invention except for the adjustable pulse widths of the stimulation pulses. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation pulses as taught by the modified Scheiner et al. with adjustable pulse widths since it was known in the art to adjust the stimulation pulse parameters in order to modify treatment for individual patient's need.

3. Claims 19, 39, 40-42, 67, 81-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (US 6,415,183), as applied to claims 30-31, 34-35, 38,

60, 75-76, 78-80 and 86 above, in view of Turcott (US 6,480,733). The modified Scheiner et al. discloses the claimed invention except for sensing hyperventilation. Turcott teaches that it is known to sense hyperventilation as set forth in columns 20 and 21, lines 56-67 and 1-26. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensed physiological signal as taught by the modified Scheiner et al. since such a modification would be useful in assessing hemodynamic status.

4. Claims 26, 45 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (US 6,415,183), as applied to claims 6, 43-44, 46-50, 54, 58, 74, 89-90, 91, 95 and 99 above, in view of Clauson et al. (US 5,423,372). The modified Scheiner et al. discloses the claimed invention except for the patient communication and interface. Clauson et al. teaches that it is known to use a LCD display and keyboard. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the programming and interface as taught by the modified Scheiner et al. with LCD display and keyboard for inputting information as taught by Clauson et al., in order to allow the patient to view their own data and utlize the keyboard to input information to the microprocessor.

5. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (US 6,415,183), as applied to claims 30-31, 34-35, 38, 60, 75-76, 78-80 and 86 above, in view of Bonnet et al. (US 5,766,228). The modified Scheiner et al. discloses the claimed invention except for the accelerometer. Bonnet et al. teaches that it is known to use enslaved active implantable devices, which adapt their actions to a

calculated or measured value of a parameter as set forth in column 1, lines 18-33. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the sensor as taught by the modified Scheiner et al. with accelerometer as taught by Bonnet et al., in order to determine the state of activity of the patient in order to properly assess the patient's present condition.

6. Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (US 6,415,183), as applied to claims 30-31, 34-35, 38, 60, 75-76, 78-80 and 86 above, in view of Meer (US 4,830,008). The modified Scheiner et al. discloses the claimed invention except for the phrenic nerve and diaphragm monitoring. Meer teaches that it is known to sense a diaphragm EMG and phrenic nerve activity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the element sensed as taught by the modified Scheiner et al. since such a modification would pinpoint a problem with the diaphragm or the phrenic nerves.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Kallok et al. (US 5,146,918) discloses a demand apnea control of central and obstructive sleep apnea.
2. Ottenhoff et al. (US 6,251,126) discloses a method and apparatus for synchronized treatment of obstructive sleep apnea.
3. Geddes et al. (US 4,827,935) discloses a demand electroventilator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M. Alter

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